apoplex medical technologies

G1.01.Requirement_proposal

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Owner: Head of R&D
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1. Responsible

Jens Meder is the contact person for this requirement. The contact person accompanies this requirement over the entire life cycle.

2. Identifier

ARC-Req2_2 : Analyse ecg data

3. Description

3.1. What should be improved/solved with the requirement?

- Analyze an ecg including all available ecg channels
  - Support for multiple ECG devices
  - Detect and annotate episodes of Atrial Fibrillation (AF) and Atrial Flutter (AFl) of 30s and more
  - Detect and annotate signal noise and artefacts in each channel
  - Calculate the atrial fibrillation burden (AF Burden) in terms of
    - the longest episode of AF/AFl measured in seconds
    - the percentage of AF/AFl, e.g., 14% for a total of 42s of af in a 300s recording
  - Calculate the Heart Rate Variability (HRV) using root mean square of successive differences (RMSSD) in milliseconds
  - Calculate the signal quality in terms of net time without artefacts or signal noise
  - Calculate the heart rate (exclude noisy areas to avoid measurement errors)
  - Analysis result is uniquely identifiable (without referencing the specific patient)

3.2. Value

- Analysis result include following information:
  - AF was correctly detected and annotated
  - Noise was correctly detected and annotated
  - Calculated AF burden
  - Calculated HRV
  - Calculated signal quality
  - Calculated heart rate
- Authorized user can access the correct result
- Authorized user generally do not need more than 20 seconds to access the result
- The user needs maximum 3 seconds to classify the result.
- A printable document format is available.

- Notes for proposal:
    - The Analysis will have a medical purpose. This makes the following steps necessary:
        - More detailed acceptance criteria will be part of the validation plan and clinical evaluation
        - Precise definition is therefore made in the corresponding process activities

3.3. Supported Devices

- Bittium Faros

4. Exemplary use case

4.1. Use Case ARC-Req2_2-Uc1 (AF)

- Personas
    - Employee in a private medical practice
    - Desktop PC of the practice
- Preconditions
    - ECG data of a patient with AF is recorded and available for analysis
- Procedure
    - The ECG data is provided for analysis.
- Expected result
    - The employee interprets the visualized analysis result as AF.

1. Approval

Approver	Date and signature
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Requirement Responsible	Jens Meder Digitally signed by Jens Meder Date: 2022.06.14 14:26:16 +02'00'
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